a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube adapted to extend below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter.

REMARKS

Claims 1 - 22 have been rejected under 35 U.S.C. §101. In response, claims 1 and 15 have been amended as suggested in the Office Action.

Claims 1 - 4, 8, 11 - 17, 19, 20, 23, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke. Brekke discloses a modified endotracheal tube that includes an inflatable cuff 20 for sealing the trachea, and an inflatable barrier 18 for sealing the back of the patient's oral cavity. Two conduits 22 and 24 (shown in figures 5 and 6 of the Brekke patent) extend along the endotracheal tube and are used to inflate the cuff 20 and barrier 18.

In response, Applicant notes that the distal end of the endotracheal tube disclosed by Brekke extends past the patient's nasopharynx, oropharynx, and larynx, and into the patient's trachea. In contrast, all of the independent claims (i.e., claims 1, 15, and 23) in the present application require that the distal end of the catheter extends "into the patient's distal nasopharynx or oropharynx" (claim 1, lines 2 - 4; claim 15, lines 2 - 4; and claim 23, lines 4 - 5). This element is neither taught nor suggested by Brekke.

All of the independent claims also require a gas flow rate of approximately 4 to 40 liters per minute (claim 1, lines 7 - 8; claim 15, lines 9 - 10; and claim 23, lines 6 - 7). This limitation is also neither taught nor suggested by Brekke, and is not an obvious design choice. Brekke teaches away from the present invention by disclosing a "closed" system

in which spontaneous breathing is blocked by the endotracheal tube cuff 20 in the patient's trachea and the inflatable barrier 18 sealing the back of the patient's oral cavity. As with other types of endotracheal tubes, the Brekke device is intended for use with a ventilator. The patient is solely dependent on the respiratory cycle and gas volume supplied by the ventilator. In contrast, the present invention is an "open" system designed to supplement a spontaneously-breathing patient's natural respiration. A high flow rate of gas (4 to 40 liters per minute) is delivered into the patient's distal nasopharynx or oropharynx, at a point relatively high in the patient's respiratory tree. A portion of this gas flows into the patient's trachea and lungs to deliver oxygen and flush carbon dioxide from the patient's lungs. In addition, if the gas delivered by the catheter has an elevated oxygen content, it will tend to enrich the oxygen content of all of the gas in the patient's respiratory tree, and thus makes the patient's spontaneous breathing more effective. However, a large portion of the gas exiting the catheter is exhaled or flows out of the patient's airway and is lost. The key point is that flow rates of 4 to 40 liters per minute are physiologically possible with "open" systems because excess gas can escape from within the patient, but not with a "closed" system such as Brekke.

With regard to claims 2 - 3, 15 - 22 and 24, nothing in Brekke teaches or suggest a catheter that can be trimmed to a desired length. The endotracheal tube disclosed by Brekke has a fixed length. The cuff at the distal end of the endotracheal tube and the conduits at the upper end of the Brekke device would make it very difficult to trim such a device while maintaining its intended functionality. Column 4, lines 46 *et seq.* of the Brekke patent discusses adjusting the position of the tube, but not trimming its length. Particularly with regard to claims 24 and 25, nothing in Brekke teaches or suggests cutting the catheter so its distal tip will have a desired position relative to the patient's uvula.

With regard to claims 23 - 28, Applicant notes that these claims specify a method for providing a supplemental flow of air/oxygen to a spontaneously breathing patient. As

previously discussed, Brekke discloses a "closed" ventilation system and teaches away from the claimed invention.

Claims 5, 6, and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al. In response, Applicant notes that all of these are dependent claims. Applicant submits that the invention defined in each of these dependent claims should be considered as a whole. The specific elements provided by each of these dependent claims should be considered in combination with the elements of their respective independent claims, rather than as isolated elements by themselves.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

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Marked Up Version of Amended Claim 1:

1. **(amended)** A nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end **adapted to extend [extending]** through a patient's nose and into the patient's distal nasopharynx or oropharynx;

a delivery tube **adapted to extend [extending]** below the patient's nostril connected to the proximal end of the nasal catheter; and

a gas source delivering a flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter.

Marked-Up Version of Amended Claim 15:

15. **(amended)** A nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end **adapted to extend [extending]** through a patient's nose and into the patient's distal nasopharynx or oropharynx, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube **adapted to extend [extending]** below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter.